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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,360	03/16/2001	Masato Horie	Q 63396	7873

7590

02/05/2003

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,360

Applicant(s)

HORIE ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20,22 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 20, 22 and 23 have been amended as requested in the amendment of Paper No. 13, filed on November 26, 2002. Claims 20, 22 and 23 are pending and under examination in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on November 26, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 20, 22 and 23 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in section 4 of Paper No.8 and in section 5 of Paper No. 10. Briefly, the instant application has provided a description of an antibody to a protein encoded by an isolated DNA. However, the instant application does not disclose the biological role of this protein or its significance.

The second Declaration of M. Horie under 37 CFR 1.132 filed on November 26, 2002 is insufficient to overcome the rejection of claims 20 and 22-23 for the following reasons.

Applicant submits that “[t]he declaration establishes that the LY6H protein shows the brain-memory forming activity” (page 4, fourth paragraph of the Response). Based on the data provided in the declaration of Horie that LY6H, which showed that knockout mice exhibit reduced memory consolidation, Applicant concludes that “the LY6H protein clearly plays an important role in memory formation of the brain”, and, further, that “the antibody [to LY6H protein] can be used for the purification of LY6H protein by immunological techniques and utilized in the screening for agonists or antagonists of LY6H protein” (page 5, third paragraph). This has not been found to be persuasive because Applicant fails to identify what is the important role of LY6H protein in “memory formation of the brain”, which would lead to a specific and substantial utility of the antibodies to LY6H protein. After complete characterization the instant gene and encoded protein may be found to have a specific biological activity. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant’s claimed invention is incomplete. Without knowing a biological role of LY6H protein there is no immediate patentable use for an antibody that binds to LY6H protein.

Claim Rejections - 35 USC § 112

6. Claims 20, 22 and 23 stand rejected under 35 U.S.C. 112, first paragraph, see reasons of record in section 4 of Paper No. 8 and section 6 of Paper No. 10. Briefly, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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7. Claim 20 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 7 of Paper No. 10.

Claim 20, as amended, encompasses an antibody which binds specifically to a protein comprising an amino acid sequence which is at least 70% homologous to the amino acid sequence of SEQ ID NO: 1. SEQ ID NO: 1 consists of 140 amino acids, therefore, the amino acid sequence that is 70% homologous to SEQ ID NO: 1 can contain as many as 45 substituted amino acids (30%), which is more than enough for the presence of an epitope that is not contained within the original SEQ ID NO: 1. Because of the presence of the term "comprising" the instant claim encompasses any antibody, which can bind to any epitope which can be expressed as a portion of a polypeptide comprising any 45 amino acids sequence not contained within SEQ ID NO:1 and, therefore, it essentially encompasses any antibody, which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody, which binds to any epitope other than an epitope, which is contained within SEQ ID NO:1 of the instant specification.

Claim Rejections - 35 USC § 102

8. Claim 20 stands rejected under 35 U.S.C. 102(b) as being anticipated by Hopp et al. U.S. Patent 5,011,912 (04.30.1991) for reasons of record in section 9 of Paper No. 10 in view of the text in section 7 of the instant office action..

Conclusion

9. No claim is allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax


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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
February 4, 2003



JOHN ULM
PRIMARY EXAMINER
GROUP 1800